al. (WO97/18320), further in view of Pariza *et al.* (US Pat. No. 5,017,614); and

4. Claims 13-17 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

Applicants believe that the following remarks traverse the Examiner's rejection of the claims.

1. Claims 5-8 Are Not Anticipated by Cain *et al.* (WO97/18320)

Claims 5-8 stand rejected under 35 U.S.C. §102 as allegedly being anticipated by Cain *et al.* (WO97/18320). The Examiner argues the following:

> Cain teaches an acylglycerol composition comprising mono- di- and tri- glyceride wherein the fatty acids are c9,t11 or t10,c12 CLA, wherein the total CLA int he composition is about 63.8%, of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer. No other isomers are indicated, or suggested to be present in the composition. (Office Action, page 3).

First, applicants note the referred to composition of Cain contains 63.8% t10,c12 and c9,t11 CLA isomers. The reference is **silent** as to what the other 36.2% of the composition comprises! Such silence cannot be taken as affirmative evidence that other isomers are not present in the composition. Applicants respectfully refer the Examiner to the accompanying Declaration of Asgeir Saebo on this point. In this declaration, Mr. Saebo refers to experiments wherein he repeated the conjugation methods disclosed in Example 6 of WO97/18320 and then analyzed the resulting CLA composition by GC-MS. These experiments demonstrate that contrary to the Examiner's position, the conjugation methods of Cain *et al.* do result in a composition containing substantial amounts of 8,10; 11,13; and trans-trans isomers.

As noted by Mr. Saebo, the results presented in Cain:

> "Do not mean that the other isomers were not present, as was found in my repeat of Cain. This discrepancy is explainable by the facts that 1) methods for the analysis of CLA compositions in 1996 were rather crude and 2) Cain may have simply chosen not to include non-active isomers when reporting their results. Improved methods for detecting the various isomers of CLA were not developed until well after the 1995

> priority date of Cain. This fact is substantiated by Yurawecz *et al.* (attached at Tab 2), who state "the CLA products analyzed in this study were found to contain up to 12 geometric and positional CLA isomers. These findings are based on appropriate and improved analytical methodologies [including gas chromatography techniques] that have only recently been developed." (Yurawecz, *p.* 281). Thus, Cain et al. may not have conducted an analysis which could detect the isomers in questions. Consideration of Example 18 of Cain et al. supports this analysis. The inventors state that their compositions, produced by the method of Example 6, contained 63.8% CLA, of which 48.9% was the cis 9, trans 10 isomer and 51.1% was the trans 10, cis 12 isomer. This means that the inventors provide no analysis of the remaining 36.2% of their composition. The 8,10; 11,13; and trans-trans isomers that are discriminated against in the present invention and detected in my repeat of Cain could well have been present in this fraction.

Thus, the Examiner's unsubstantiated conclusion that "No other isomers are indicated, or suggested to be present in the composition" of Cain has been rebutted by actual experimental evidence. Indeed, Cain does not teach the claimed compositions which contain less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R_1, R_2, and R_3 of an acylglyceride. Applicants further note that Mr. Saebo's Declaration directly rebuts the Examiners statements on pages 6 and 7 of the Office Action regarding the Yurawecz and Cain references and provide evidence that compositions in the cited reference contained the undesired 8,10; 11,13; and trans-trans isomers.

Applicants further note that any reliance by the examiner on anticipation by inherency principals are misfounded. The Federal Circuit has stated that inherency cannot be assumed based upon information provided in the disclosed invention. Indeed, to establish inherency the prior art must have recognized at the time of the Applicant's invention, that the elements now at issue were inherently present in the Examiner's reference. For example, in *Continental Can Co. USA v. Monsanto Co.*, the Federal Circuit held that:

> To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill.

(*Continental Can Co. USA v. Monsanto Co.*, 212 USPQ 323 [CCPA 1981]; emphasis added). Furthermore, "[i]n relying upon the theory of inherence, the examiner must provide a basis in fact/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." (MPEP §2112, quoting, *In re Robertson*, 169 F.3d 743 [Fed. Cir. 1999]; emphasis original). Applicants again submit, that since the prior art at the time of Applicants' invention did not recognize compositions or methods of producing compositions comprising less than 1% of particular CLA isomers that the cited reference does not anticipate the presently claimed invention.

Accordingly, Applicants respectfully request that this ground of rejection be removed and the claims passed to allowance.

2. Claims 13-17 Are Not Obvious Over WO97/18320

Claims 13-17 stand rejected under 35 U.S.C. §103 as allegedly being obvious over Cain *et al.* (WO97/18320). Applicants respectfully note that a *prima facie* case of obvious requires that all elements of the claims be present in the cited reference. The Examiner states that "Particularly, Cain et al. have characterized all of the fatty acid through gas chromatography and have identified the CLA." As detailed above, Mr. Saebo's Declaration, contrary to the Examiner's findings, establishes that the CLA compositions of Cain et al. contained substantial levels of 8,10; 11,13; and trans-trans isomers. As Mr. Saebo emphasizes, this discrepancy is probably due to the inadequacy of the analytical methods utilized by Cain et al. Thus, because Cain et al. does not teach methods of obtaining compositions which contain less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R_1, R_2, and R_3 in an acylglyceride as required by the claims, the claims cannot be obvious in view of Cain et al. Accordingly, Applicants respectfully request that this ground of rejection be removed and the claims passed to allowance.

3. Claims 5-8 and 13-17 Are Not Obvious Over the Combination of Nilsen, Cain and Pariza

Claims 5-8 and 13-17 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious under Nilsen *et al.* (U.S. Pat. No. 5,885,594) in view of Cain *et al.* (WO97/18320),

further in view of Pariza *et al.* (US Pat. No. 5,017,614). To establish a finding of *prima facie* obviousness, the Examiner must show by a "**preponderance of the evidence**" that the claimed invention is obvious in view of the evidence presented by the Examiner. (MPEP §2142). "The legal standard of '**a preponderance of the evidence**' requires . . . the examiner provide evidence which as a whole shows that the legal determination sought to be proved (*i.e.*, the reference teachings establish a *prima facie* case of obviousness) is more probable than not." (MPEP §2142; emphasis added).

The Examiner is well aware that are three base line requirements that **must** be satisfied in order to meet the evidentiary burdens requisite for establishing a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, at the time of invention there was a reasonable expectation of success should the combination be carried out. (MPEP §2143.02). Third, the references must teach or suggest every claim element. (*In re Royka*, 490 F.2d 981 (CCPA 1974); *See also,* MPEP §2143.03). This evaluation requires "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." (*In re Wilson*, 424 F.2d 1382,1385 (CCPA 1970)).

Failure to establish any one of these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicants to allowance of the claims at issue. (*See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321 (Fed. Cir. 1990)). Applicants submit that even if the references are combined (wrongfully) they do not teach every claim element. In addressing this rejection, Applicants focus on the independent claims since non-obviousness of an independent claim necessarily leads to non-obviousness of claims dependent therefrom.[3]

The Examine has failed to establish a prima facie case of obviousness because the references, alone or in combination, fail to teach each element of the claimed compositions. Applicants first note that as discussed in detail above, Cain et al. does not teach compositions comprising less than 1% 8,10; 11,13; and trans-trans isomers or methods of obtaining such compositions. Likewise, Nilsen et al. provides no such compositions or methods. Indeed,

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[3] §MPEP 2143.03.

Nilsen et al. **do not teach any method** at all for conjugation, they merely list CLA in a long list of fatty acids that may be useful in their invention. This fact is verified in paragraph 6 of the Saebo Declaration. Pariza et al. further fails to cure this deficiency. The Examiner states that "Pariza is cited to show that the person of ordinary skill in the art possesses the skill of preparing/or isolating the pure single isomer employed herein." (Office Action, p. 5.) However, as substantiated in the Saebo Declaration, the methods employed by Pariza are HPLC methods designed for the purification of small amounts of materials for use as chromatography standards. There is no teaching that these materials are suitable for use (or can be prepared in appropriate quantities) in the production of acyglycerols. Furthermore, there is absolutely no suggestion to mix the isomers once they have been purified. Thus, none of the three references teach an acylglyceride composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R_1, R_2, and R_3.

Applicants further note that the Examiner has stated on page 7 of the Office Action that:

> The instant invention relies on the limitation "less than 1%" of the other isomers as the point of novelty, without illustrating how this limitation make [sic] the claimed invention patentably distinct from the prior art. Lacking the criticality of such limitation, the claimed invention would be properly rejected over Nilsen et al., in view of Cain et al., further in view of Pariza et al.

In response, Applicants respectfully refer the Examiner to paragraphs 8 and 9 of the Saebo Declaration. The literature, even 3 years after the priority date of the present application, recognized that the presence of unwanted isomers in CLA products was a problem. As stated in Adlof et al., Changes in Conjugated Linoleic Acid Composition Within Samples Obtained from a Single Source, Lipids 36(3):315-17 (2001):

> If indeed certain daily levels of CLA intake are required to produce suggested health benefits in humans, changes in concentrations of specific CLA isomers could significantly impact these effects. Care must be taken to analyze the CLA used in human and animal studies.

Applicants recognized this problem before anyone else and developed methods to avoid the problem. It is well settled in patent law that "[i]t should not be necessary . . . to point out that a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified." (*In re Sponnable*, 405 F.2d 578, 585 (C.C.P.A. 1969); *In re Kosei Nomiya et al.*, 509 F.2d 566, 571 (C.C.P.A. 1975)). Thus, the 1% limitation is critical and limitation of the unwanted isomers provides a tangible benefit.

Accordingly, Applicants respectfully request that this ground of rejection be removed and the claims passed to allowance.

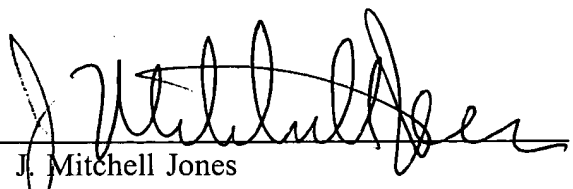
4. The Claims Are Definite

Claims 13-17 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicants respectfully disagree. Nevertheless, without acquiescing to the Examienr's rejections and in order to further the business interests of the Applicants, Claim 13 has been amended in line 6 to refer to acylglycerols compositions. Applicants respectfully submit that this amendment makes the claims definite. Applicants note that this amendment does not affect the scope of the claims. Accordingly, the claims are in condition for allowance.

CONCLUSION

All grounds of rejection of the Final Office Action of November 29, 2001, have been addressed, and therefore reconsideration of the application is respectfully requested. It is respectfully submitted that the claims are in condition for allowance. Should the Examiner have any questions, or if a telephone conference would aid in the prosecution of the present application, the Applicants encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: December 13, 2002



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APPENDIX I
MARKED-UP VERSION OF REWRITTEN, ADDED, AND/OR CANCELLED CLAIMS

13. (Amended four times) A composition comprising a prepared food product containing a biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R_1, R_2, and R_3 attached at the positions of the OH- groups of a glycerol backbone, and wherein R_1, R_2, and R_3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said acylglycerol composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R_1, R_2, and R_3, wherein said percentages are peak area percentages as determined by gas chromatography.

APPENDIX II

CLEAN VERSION OF THE ENTIRE SET OF PENDING CLAIMS AS AMENDED IN THIS COMMUNICATION

13. (Amended four times) A composition comprising a prepared food product containing a biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R_1, R_2, and R_3 attached at the positions of the OH- groups of a glycerol backbone, and wherein R_1, R_2, and R_3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said acylglycerol composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R_1, R_2, and R_3, wherein said percentages are peak area percentages as determined by gas chromatography.

6. The composition of claim 5, further comprising a food product incorporating said acylglycerol composition.

7. The composition of claim 6, wherein said food product is for human consumption.

8. The composition of claim 6, wherein said food product is a feed formulated for animal consumption.

13. (Amended three times) A composition comprising a prepared food product containing a biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R_1, R_2, and R_3 attached at the positions of the OH- groups of a glycerol backbone, and wherein R_1, R_2, and R_3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less

than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R_1, R_2, and R_3, wherein said percentages are peak area percentages as determined by gas chromatography.

14. The composition of Claim 13, wherein said prepared food product is a bar.

15. The composition of Claim 13, wherein said prepared food product is a drink.

16. The composition of Claim 13, wherein said prepared food product is a snack food.

17. The composition of Claim 13, wherein said prepared food product is a frozen meal.